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DRUG DISCOVERY

FDA approved drugs – January 2013

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1. KYNAMRO (MIPOMERSEN SODIUM)

1.1. Company
Genzyme; Approved by January 2013

1.2. Treatment Area
Homozygous familial hypercholesterolemia

1.3. General Information
Kynamro (mipomersen sodium) inhibits the ApoB-100 molecule, a protein that plays a pivotal role in the production of low-density lipoprotein (LDL). It reduces LDL-C by preventing the formation of atherogenic lipoproteins, the particles that carry cholesterol through the bloodstream. It is specifically indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol 31 (TC), and non-high density lipoprotein-cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). It is supplied as a solution for subcutaneous injection. The recommended dose is 200 milligrams (mg) once weekly.

1.4. Mechanism of Action
Mipomersen is an antisense oligonucleotide targeted to human messenger ribonucleic acid (mRNA) for apo B-100, the principal apolipoprotein of LDL and its metabolic precursor, VLDL. It is complementary to the coding region of the mRNA for apo B-100, and binds by Watson and Crick base pairing. The hybridization of mipomersen to the cognate mRNA results in RNase H-mediated degradation of the cognate mRNA thus inhibiting translation of the apo B-100 protein.

1.5. Side Effects
Adverse events associated with the use of Kynamro: injection site reactions, flu-like symptoms, nausea, headache and elevations in serum transaminases.

2. NESINA (ALOGLIPTIN)

2.1. Company
Takeda Pharmaceuticals U.S.A; Approved by January 2013

2.2. Treatment Area
Type II diabetes mellitus

2.3. General Information
Nesina (alogliptin) is a small-molecule. It is specifically indicated as an adjunct to diet and exercise to improve glycemic control in adults with type II diabetes mellitus. It is supplied as a tablet for oral administration. The recommended dose is 25 mg once daily, with or without food.

2.4. Mechanism of Action
Nesina (alogliptin) is an orally available dipeptidyl peptidase IV (DPP IV) inhibitor. DPP-4 inhibitors slow the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic peptide), both of which play a role in regulating blood glucose levels.

2.5. Side Effects
Adverse events associated with the use of Nesina include: nasopharyngitis, headache, upper respiratory tract infection.

3. FLUBLOK (SEASONAL INFLUENZA VACCINE)

3.1. Company
Protein Sciences; Approved by January 2013

3.2. Treatment Area
Influenza virus subtypes A and type B

3.3. General Information
Flublok (seasonal influenza vaccine) is a trivalent recombinant vaccine for seasonal influenza, made without the use of eggs or the live influenza virus. It contains recombinant HA proteins of the three strains of influenza virus specified by health authorities for inclusion in the annual seasonal vaccine. It is specifically indicted for active immunization against disease caused by influenza virus subtypes A and type B contained in the vaccine, for use in adults 18 through 49 years of age. It is supplied as a solution for intramuscular injection. It should be administered as a single 0.5-mL dose.

3.4. Mechanism of Action

Brithvi V,
FDA approved drugs – January 2013,
Drug discovery, 2013, 3(9), 41-42,

Flublok is a trivalent recombinant vaccine contains recombinant HA proteins which function as antigens induce a humoral immune response, measured by hemagglutinin inhibition antibody. The exclusion of eggs and live viris allows Flublok to be made quickly and without any of the infectious risk traditionally associated with vaccine manufacture. Flublok is highly purified, has three times the amount of active ingredient in traditional influenza vaccines, and contains no preservatives (thimerosal), antibiotics or adjuvants.

3.5. Side Effects
Adverse events associated with the use of Flublok include: injection-site reaction, headache, fatigue, and myalgia

4. DRUG NAME: UCERIS (BUDESONIDE)

4.1. Company
Santarus; Approved by January 2013

4.2. Treatment Area
Ulcerative colitis

4.3. General Information
Uceris (budesonide) is an oral, extended release formulation of budesonide, a synthetic corticosteroid. It was formulated to delay the release of the active ingredient until the tablet reaches the indicated intestinal location where the controlled dissolution begins, where it decreases inflammation in the digestive tract. Budesonide retains the effectiveness of classical corticosteroids, but with reduced side effects due to its targeted controlled release in the colon with minimal systemic absorption. It is specifically indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis. It is supplied as a tablet for oral administration. The recommended dose is 9 mg taken orally once daily in the morning with or without food for up to 8 weeks. It should be swallowed whole and not chewed, crushed or broken.

4.4. Mechanism of Action
Uceris (budesonide) formulation contains budesonide in an extended release tablet core. The tablet core is enteric coated to protect dissolution in gastric juice which delays budesonide release until exposure to a pH > 7 in the small intestine. Upon disintegration of the coating, the core matrix provides extended release of budesonide in a time dependent manner.

4.5. Side Effects
Adverse events associated with the use of Uceris include: headache, nausea, decreased blood cortisol, upper abdominal pain, fatigue, flatulence, abdominal distension, acne, urinary tract infection, arthralgia, constipation.

5. KINERET (ANAKINRA)

5.1. Company
Swedish Orphan Biovitrum; Approved by January 2013

5.2. Treatment Area
Cryopyrin-Associated Periodic Syndromes

5.3. General Information
Kineret (anakinra) is an intravenous recombinant, nonglycosylated form of human interleukin-1 receptor antagonist (IL-1Ra). It is specifically indicated for Neonatal-Onset Multisystem Inflammatory Disease, a severe form of Cryopyrin-Associated Periodic Syndromes. It is supplied as a solution for subcutaneous injection. The recommended starting dose is 1-2 mg/kg. The dose can be individually adjusted to a maximum of 8 mg/kg daily to control active inflammation.

5.4. Mechanism of Action
Kineret (anakinra) blocks the biologic activity of IL-1 alpha and beta by competitively inhibiting IL-1 binding to the interleukin-1 type I receptor (IL-1RI), which is expressed in a wide variety of tissues and organs. IL-1 production is induced in response to inflammatory stimuli and mediates various physiologic responses including inflammatory and immunological responses. Spontaneous mutations in the CIAS1/NLRP3 gene have been identified in a majority of patients with cryopyrin-associated periodic syndromes such as NOMID. CIAS1/NLRP3 encodes for cryopyrin, a component of the inflammasome. The activated inflammasome results in proteolytic maturation and secretion of IL-1ß, which has an important role in the systemic inflammation and manifestations of NOMID.

5.5. Side Effects
Adverse events associated with the use of Kineret include: injection site reaction, headache, vomiting, arthralgia, pyrexia, and nasopharyngitis

6. VARIZIG, VARICELLA ZOSTER IMMUNE GLOBULIN (HUMAN)

6.1. Company
Cangene; Approved by January 2013

6.2. Treatment Area
varicella zoster (chickenpox)

6.3. General Information
VariZIG (Varicella Zoster Immune Globulin (Human)) provides passive immunization for non-immune individuals exposed to VZV, reducing the severity of varicella infections. It is specifically indicated for post-exposure prophylaxis of varicella in high risk individuals. High risk groups include: immunocompromised children and adults, newborns of mothers with varicella shortly before or after delivery, premature infants, neonates and infants less than one year of age, adults without evidence of immunity and pregnant women. It is supplied as a solution for intramuscular administration. It should be administered as soon as possible following varicella zoster virus (VZV) exposure, ideally within 96 hours for greatest effectiveness. Dosing of VariZIG is based on body weight. See label for recommendations. The minimum dose is 62.5 International Units (IU) for small infants under two kilograms body weight; the maximum dose of 625 IU should be administered for all patients greater than 40 kilograms in weight.

6.4. Mechanism of Action
VariZIG, Varicella Zoster Immune Globulin (Human) is a solvent/detergent-treated sterile lyophilized preparation of purified human immune globulin G (IgG) containing antibodies to varicella zoster virus (anti-VZV). VZV is the causative agent of chickenpox. Varizig is prepared from plasma donated by healthy, screened donors with high titers of antibodies to VZV, which is purified by an anion-exchange column chromatography manufacturing method. This donor selection process includes donors with high anti-VZV titers due to recent natural infection by VZV, or due to recurrent zoster infection (shingles).

6.5. Side Effects
Adverse events associated with the use of VariZIG include: pain at the injection site, headache.

Brithvi V,
FDA approved drugs – January 2013,
Drug discovery, 2013, 3(9), 41-42,